

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: LISA D. HANIN	)	Examiner: T. Sweet (parent appl.)
	)	
Serial Number: Pending	)	
	)	Art Unit: 3738 (parent appl.)
Filed: Herewith	)	
	)	Confirmation No.
For: SURFACE TOPOGRAPHY	)	
METHOD FOR DETERMINING	)	
EFFECT OF A BOTULINUM	)	
TOXIN UPON A MUSCLE	)	
<hr/>		Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop: Patent Application  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled SURFACE TOPOGRAPHY METHOD FOR DETERMINING EFFECT OF A BOTULINUM TOXIN UPON A MUSCLE, one copy of documents of which she is aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 1 page Information Disclosure Citation (Form PTO-1449). Applicant also encloses a copy of Form PTO-1449, without the cited art, which was submitted in the parent application serial number 10/099,602.

While these documents may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material

documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: September 12, 2003

Stephen Donovan  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed therein are being deposited with the United States Postal Service on September 15, 2003 in an envelope as "Express Mail Post Office To Addressee" mailing label number EV295682982US with sufficient postage for Express Mail addressed to Mail Stop: Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: September 15, 2003

Susan Bartholomew

Name of person mailing paper

Susan Bartholomew  
Signature of person mailing paper

### LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17493CIP1 (BOT)	SERIAL NO.: Pending
APPLICANT: LISA D. HANIN	TITLE: SURFACE TOPOGRAPHY METHOD FOR DETERMINING EFFECT OF A BOTULINUM TOXIN UPON A MUSCLE
FILING DATE: herewith	GROUP: 3738 (parent appl.)

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,183,462	2/2/93	Borodic			
	AB						
	AK						

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATI ON (yes/no)
	BA						No

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Guerrissi, Jorge, et al., <b>Local Injection into Mimetic Muscles of Botulinum Toxin A for the Treatment of Facial Lines</b> , <i>Annals of Plastic Surgery</i> , Vol 39, No 5, Nov 1997, pp 447-453
	CB	Hamjian, J.A., et al., <b>Serial Neurophysiological Studies of Intramuscular Botulinum-A toxin in Humans</b> , Muscle & Nerve, December 1994 pgs. 1385-1392
	CC	Koman, L.A., et al., <b>Spasticity Associated with Cerebral Palsy in Children</b> , Therapy in Practice, Pediatr Drugs, 2003
	CD	
	CE	
	CF	
	CG	
	CH	
	CI	

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_  
 \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17493 (BOT)	SERIAL NO.: 10/099,602
APPLICANT: LISA D. HANIN	TITLE: METHOD FOR DETERMINING EFFECT OF A CLOSTRIDIAL TOXIN UPON A MUSCLE
FILING DATE: March 14, 2002	GROUP: 3739

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,437,291	8/1/95	Pasricha, et al.			
	AB	5,670,484	9/23/97	Binder			
	AC	5,714,468	2/3/98	Binder			
	AD	5,766,606	6/16/98	Brady			
	AE	5,989,545	11/23/99	Foster, et al.			
	AF	6,063,768	5/16/00	First			
	AG	6,113,915	9/5/00	Aoki, et al.			
	AH	6,139,845	10/31/00	Donovan			
	AI	6,143,306	11/7/00	Donovan			
	AJ	6,261,572 B1	7/17/01	Donovan			
	AK	6,265,379 B1	7/24/01	Donovan			

**FOREIGN PATENT DOCUMENTS**

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	BA	DE19852981 A1	5/18/00	Germany			No
	BB	WO 96/33273	10/24/96	PCT			
	BC	WO 98/07864	2/26/98	PCT			
	BD	WO 99/03483	1/28/99	PCT			
	BE	WO 99/17806	4/15/99	PCT			
	BF	WO 00/10598	3/2/00	PCT			
	BG	WO 00/15245	3/23/00	PCT			
	BH	WO 00/24419	5/4/00	PCT			
	BI	WO 00/57897	10/5/00	PCT			
	BJ	WO 00/62746	10/26/00	PCT			
	BK	WO 00/74703 A2	12/14/00	PCT			
	BL	WO 01/21213 A2	3/29/01	PCT			

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DATE CONSIDERED

10/29/02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

OTHER ART

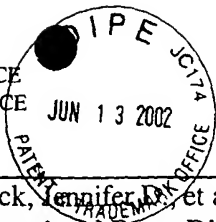
(Including Author, Title, Date, Pertinent Pages, etc.)

CA	Aoki, R., et al., <b>Preclinical update on BOTOX® (botulinum toxin type A)-purified neurotoxin complex relative to other botulinum neurotoxin preparations</b> , <i>European Journal of Neurology</i> , 1999 6 (suppl 4): S3-S10
CB	Brach, Jennifer S. et al., <b>Measuring Fatigue Related to Facial Muscle Function</b> , <i>Arch Phys Med Rehabil</i> , Vol 76, Oct. 1995, pp 95-98
CC	Carruthers, J. et al, <b>Treatment of Glabellar Frown Lines with C. Botulinum -A Exotoxin</b> , <i>J. Dermatol Surg Oncol</i> , 1992 Jan; 18(1):17-21
CD	Corcuff, P. et al., <b>Skin relief and aging</b> , <i>J. Soc. Cosmet. Chem</i> , 34, (July 1983), pp 177-190
CE	Doggweiler, R., <b>Botulinum toxin type a causes diffuse and highly selective atrophy of rat prostate</b> , <i>Neurourol Urodyn</i> , 1998; 17(4): 363
CF	Dressler, D. et al., <b>Electromyographic Quantification of the Paralysing Effect of Botulinum Toxin in the Sternocleidomastoid Muscle</b> , <i>European Neurology</i> , 2000; 43, pp 13-16
CG	Fauci, Anthony et al., <i>Harrison's Principles of Internal Medicine</i> , 14 <sup>th</sup> Edition, 1998 by McGraw Hill
CH	Fridlund, Alan, et al., <b>Guidelines for Human Electromyographic Research</b> , <i>The Society for Psychophysiological Research, Inc.</i> , Vol 23, No 5, 1986, pp 567-589
CI	Grove, Gary L. et al., <b>Objective Methods for Assessing Skin Surface Topography Noninvasively</b> , <i>Cutaneous Investigation in Health and Disease</i> , 1989 by Marcel Dekker, Inc., Chapter One, pp 1-32
CJ	Grove, Gary L. et al., <b>Skin replica analysis of photodamaged skin after therapy with tretinoin emollient cream</b> , <i>Journal of the American Academy of Dermatology</i> , Vol 25, No 2, Part 1, Aug 1991, pp 231-237
CK	Guerrissi, Jorge, et al., <b>Local Injection into Mimetic Muscles of Botulinum Toxin A for the Treatment of Facial Lines</b> , <i>Annals of Plastic Surgery</i> , Vol 39, No 5, Nov 1997, pp 447-453
CL	Heckmann, Marc, et al., <b>Quantification of the efficacy of botulinum toxin type A by digital image analysis</b> , <i>J Am Acad Dermatol</i> , 2001, 45, PP 508-514, Published online 5/23/2001, pp 1-7
CM	Johnson, Eric A., <b>Biomedical Aspects of Botulinum Toxin</b> , <i>J.Toxicol Toxin Reviews</i> , 18(1) 1999, pp 1-15, Abstract
CN	Leyden, James J., et al., <b>Treatment of photodamaged facial skin with topical tretinoin</b> , <i>Journal of the American Academy of Dermatology</i> , Vol 21, No 3, Part 2, 9/1989, pp 638-644

EXAMINER

DATE CONSIDERED

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	CO	Pennock, Jennifer D., et al., Relationship between Muscle Activity of the Frontalis and the Associated Brow Displacement, <i>Plast Reconstr Surg</i> , 1999 Nov, 104 (6) pp 1789-1787
	CP	Senior, M.A., Botox and the management of pectoral spasm after subpectoral implant insertion, <i>Plast. Reconstr. Surg</i> 2000 July; 106,(1) pp. 224-225
	CQ	Tassinary, Louis G., et al., A Psychometric Study of Surface Electrode Placements for Facial Electromyographic Recording: I. The Brow and Cheek Muscle Regions, <i>Psychophysiology</i> , 1989, Vol 26, No 1, pp 1-16, Abstract
	CR	Van Boxtel, A., et al., Amplitude and Bandwidth of the Frontalis Surface EMG: Effects of Electrode parameters, <i>Psychophysiology</i> , 1984, Vol 21, No 6, pp 699-707, Abstract
	CS	Vitti, Mathias, et al., Electromyographic Investigation of Procerus and Frontalis Muscles, <i>Electromyogr. Clin. Neurophysiol.</i> , 1976, 16, pp 227-236

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**Notic of References Cited**

Application/Control No.

10/099,602

Applicant(s)/Patent Under  
Reexamination  
HANIN, LISA D.

Examiner

Thomas J Sweet

Art Unit

3738

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Guerrissi et al (Journal article from the Annals of Plastic Surgery 1997 39/5 (447-453)).
	V	J. O Guerrissi, injection of botulinum toxin A into orbicularis oculi muscle for the treatment of crow's feet., and the discussion thereof, Plastic and reconstructive surgery (United States) May 2000, 105 (6) (2219-2228)
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**Notice of References Cited**

Application/Control No.

10/099,602

Applicant(s)/Patent Under  
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HANIN, LISA D.

Examiner

Thomas J Sweet

Art Unit

3738

Page 1 of 1

U.S. PATENT DOCUMENTS

**RECEIVED**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,758,730	07-1988	Bazin et al.	250/559.22
	B	US-3,689,668	09-1972	Emile Leon Piette et al.	514/555
	C	US-4,997,657	03-1991	Horrobin et al.	424/401
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Blitzer et al (Journal abstract from the Archives of Otolaryngology-- Head & Neck Surgery 1997 Apr; 123(4): 389-92.)
	V	Pribitkin et al (Journal abstract from the Archives of Otolaryngology-- Head & Neck Surgery 1997 Apr; 123(4): 321-26.)
	W	Guerrissi et al (Journal abstract from the Annals of Plastic Surgery 1997 39/5 (447-453)).
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
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